DETAILED ACTION

The amendment filed 10/06/2011 is acknowledged.

Claims 1-20 are pending.

Claims 17-20, drawn to non-elected inventions, are withdrawn from consideration.

Claims 1-16 are examined on the merits.

Claim Rejections Withdrawn:

Claim Rejections - 35 USC § 112-second paragraph

The rejection of claims 14, 15 and 16 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is WITHDRAWN in view of the amendment to the claims.

Claim Rejections - 35 USC § 102

The rejection of claims 1-4 rejected under 35 U.S.C. 102(b) as being anticipated by Santos-Rosa (Santos-Rosa, H., et al., Nature, 419, 407-411, 2002) is WITHDRAWN in view of the amendment to the claims.

The rejection of claims 1, 2, 4, 6-8 and 12 rejected under 35 U.S.C. 102(b) as being anticipated by WO 02/092002; cited in the IDS) is WITHDRAWN in view of the amendment to the claims.

The rejection of claims 1, 2, 4, 8 and 15 under 35 U.S.C. 102(e) as being anticipated by Huang (US 6,955,905; issued Oct. 18, 2005; effective filing date Jul. 18, 2001) is WITHDRAWN in view of the amendment to the claims. Huang does not teach a polypeptide that comprises both SEQ ID NO: 52 and 53, as required by the claims.

Claim Rejections - 35 USC § 103

The rejection of claim 16 under 35 U.S.C. 103(a) as being unpatentable over Huang (supra) is WITHDRAWN in view of the amendment to claim 16.

New Grounds of Rejection:

Claim Objections

Claim 12 is objected to because of the following informalities: grammatical error. The word "decrease" should be replaced with "decreases". Appropriate correction is required.

The following rejection is necessitated by the amendment of claims 15 and 16.

Claim Rejections - 35 USC § 112-first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 15 and 16 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not

described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a Written Description rejection.

Claims 15 and 16 are drawn, in part, to kits comprising and methods using polypeptides characterized as a polypeptide comprising a portion of the amino acid sequence of SEQ ID NO: 51 wherein the polypeptide comprises both SEQ ID NO: 52 and SEQ ID NO: 53 wherein the polypeptide binds to S-adenosyl-L-methionine. The amino acid sequences of both SEQ ID NO: 52 and SEQ ID NO: 53 are included within the amino acid sequence of SEQ ID NO: 51. Claims 15 and 16 are drawn to kits and methods using a genus of polypeptides that includes species with large structurally uncharacterized regions. The amino acid sequence of SEQ ID NO: 51 is 428 amino acids in length, whereas SEQ ID NO: 52 is 7 amino acids in length and SEQ ID NO: 53 is 8 amino acids in length.

For a claim drawn to a genus, the written description requirement may be satisfied through sufficient description of a representative number of species by actual reduction to practice or by disclosure of relevant, identifying characteristics, i.e. structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus. A "representative number of species" means that the species, which are adequately described, are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus (see Official Gazette 1241 OG 174, January 30, 2001).

The specification provides the structure of ZNFN3A1 (SEQ ID NO: 51). However, the claims encompass using polypeptides that may vary significantly from the amino acid sequence of SEQ ID NO: 51 because only 15 amino acids of the polypeptides are described. The specification provides mutant-type ZNFN3A1 (page 29, Table 3). However, the mutants provides are not representative of the genus of polypeptides comprising minimally SEQ ID NO: 51 together with SEQ ID NO: 53, wherein the polypeptides bind to S-adenosyl-L-methionine, and have the required methyltransferase activity for the claimed assays and kits. While the specification teaches that the presence of both SEQ ID NO: 52 and SEQ ID NO: 53 are necessary for binding, the specification does not teach if these regions are sufficient for binding to S-adenosyl-L-methione, and sufficient to exhibit the required methyl transferase activity for the claimed assays and kits. Additionally, other activities for ZFN3A1 are described in the specification. However, for the methyltransferase activity or any of the other activities of ZFN3A1, there is no correlation between activity and amino acid sequence described; i.e. the specification does not describe which changes to the sequence of SEQ ID NO: 51 can be made while retaining biological activity.

Therefore, the specification does not provide a representative number of species by actual reduction to practice, because the two mutants provided did not have methyltransferase activity. Additionally, the specification does not provide a disclosure of relevant, identifying characteristics coupled with a known or disclosed correlation between function and structure, because the specification does not disclose which amino acids may be changed while still preserving methyltransferase activity or any of the other biological activities of ZNF3A1. Thus, one of skill in the art would not recognize that applicant was in possession of the claimed

invention which encompasses portions of SEQ ID NO: 51 minimally comprising SEQ ID NO: 52 and SEQ ID NO: 53, wherein any of these portions has a biological activity equivalent to a polypeptide consisting of the amino acid sequence of SEQ ID NO: 51.

Claim Rejections Maintained:

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

The rejection of claims 1, 4, 6- 8, 12, 15 and 16 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3 of US 7,968,281 is made for the reasons of record for the previous provisional rejection. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1-3 are drawn to methods for identifying an agent that modulates methylation of a retinoblastoma peptide by SMYD3, wherein SMYD3 is a polypeptide comprising SEQ ID NO: 2, which is the same as SEQ ID NO: 51 recited in the methods of identifying an agent, and kits of the instant claims. Therefore, claims 1-3 are encompassed by the claims of the instant application.

Applicants' remarks with respect to holding this rejection in abeyance until allowable subject matter is identified is acknowledged.

Conclusion

Claims 2, 3, 5, and 9-11 are objected to for depending from a rejected claim. Claims 13 and 14 are allowable.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne Holleran, whose telephone number is (571) 272-0833. The examiner can normally be reached on Monday through Friday from 9:30 am to 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Misook Yu, can be reached on (571) 272-0839. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Official Fax number for Group 1600 is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll free).

Anne L. Holleran
Patent Examiner
/Alana Harris Dent, Ph.D./
Primary Examiner, Art Unit 1643